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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/105,117 06/17/98 VRLIJC

M FJ-122

EXAMINER

HM12/1022

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ART UNIT	PAPER NUMBER

1653

DATE MAILED:

10/22/01

25

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/105,117

Applicant(s)

VRLIJC ET AL.

Examiner

Rita Mitra

Art Unit

1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
 Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 August 2001.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-48 is/are pending in the application.
- 4a) Of the above claim(s) 21-42 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 and 43-48 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892)
- 16) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 18) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other:

DETAILED ACTION

The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1653.

Election/Restriction

Applicants' election with traverse of Group I (claims 1-20) in paper #33 (filed on August 3, 2001) is acknowledged. The traversal is on the ground that in accordance with PCT requirements there is clearly unity between the process and the product claims as presented in the present application. The traversal has been fully considered and claims 43-48 of Group V have been rejoined with claims 1-20 of Group I.

Claims 21-42 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a non-elected invention. Therefore, claims 1-20 and 43-48 are currently pending and are under examination.

Priority

Applicant's claim for foreign priority under 35 U.S.C. 119 (a-d) is acknowledged. This application is a 371 of PCT/DE96/02485 filed on December 18, 1996, which claims a priority of a foreign application 195 48 222.0 filed on December 22, 1995. However, the instant application fails to provide a copy of these applications and certified English translations in support of the priority date claimed. Therefore, the priority date granted is June 17, 1998.

Claim Rejections - 35 USC § 112, First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 8-10 and 16-18 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claims 8 and 16 and the dependent claims 9, 10 and 17, 18 thereto are directed to a process for the microbial production of amino acids using a gene construct, wherein the regulatory gene of the construct includes a nucleotide sequence as set forth in SEQ ID NO: (B) 3 and the allelic variants thereof. The specification describes at page 6 as "allelic variations or, respectively, equally effective DNA sequences comprise particularly functional derivatives which can be obtained by deletions, insertion or substitution of nucleotides of corresponding sequences..." However the specification at page 6, lines 7-19 describes a functional derivative that can be obtained by mutation but it does not provide a definition of an allelic variant. According to Ayala et al. (Modern Genetics, Glossary), an allele is "one of two or more alternative forms of a gene, each possessing a unique nucleotide sequence; different alleles of a given gene are usually recognized, however, by the phenotypes rather than by comparison of their nucleotide sequences." The specification does not describe what might be considered an allele of the DNA of claims 8 and 16 or provide any examples of the same. It does not appear that allelic variants have been isolated or identified. There are no examples of allelic sequences of the claimed DNA to which one could compare undisclosed DNA to determine if they are also alleles. For these reasons the claimed allelic variants have not been adequately described, and a

person having ordinary skill in art would not recognize a specific utility for the allelic variants and would not know how to use them.

Claim Rejections - 35 USC § 112, Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

“The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.”

Claims 1-20, 44 and 45 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is indefinite because it lacks essential steps as claimed in the process for the microbacterial production of amino acids. The omitted steps are: the method of construction of a gene construct, insertion of the construct into a suitable vehicle and transformation of a suitable host cell, culturing the transformed cells and recovering the amino acids from the culture, and a step whereby the desired outcome can be determined. Claims 2-20 are included in the rejection because they are dependent on rejected claim and do not correct the deficiency of the claim from which they depend.

Claims 3 and 44 are indefinite as to the “mutants.” The term “mutated export gene” renders the claim indefinite. It is not clear what kind of mutants they are, e.g. what kind of a modification is made on the export gene sequence and whether those mutants are retaining the activity of the intact export gene. Claims 4 and 45 are included in the rejection because they are dependent on rejected claims and do not correct the deficiency of the claim from which they depend.

Claim 13 is indefinite because of the term “central metabolism metabolites.” The term “central metabolism metabolites” renders the claim indefinite. It is not clear what the central metabolism metabolites are and what is its “increased part.” Claim 14 is included in the rejection because it is dependent on a rejected claim and does not correct the deficiency of the claim from which it depends.

Claim Rejections – 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-20 and 43-48 are rejected under 35 USC 102 (b) as being anticipated by Vrljic et al. (Molecular Microbiology, vol. 22(5), pp 815-826, 1996). Vrljic et al. teach a L-lysine export from *Corynebacterium glutamicum* by identifying lysE which encodes the translocator specifically exporting L-lysine from the cell (see ‘summary’ in col. 1, page 815, ‘subcloning and sequence analysis’ in col. 2, page 816 and Fig. 2, page 817). LysE is considered for the export gene used in the method of microbial production of amino acids as claimed in claims 1-20 and 43-48, thus anticipating the claims of instant application. Vrljic et al. also teach a mutant of export gene that excreted L-lysine at an increased rate, see under ‘lysE and its protein are required for export’, col 1, page 819 and Fig 1 (claims 3 and 44), a vector pUC where *C. glutamicum* export gene DNA is inserted, see col 1, page 823 (claim6). Further, Vrljic

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et al. teach a regulatory gene *lysG*, which is a transcriptional regulator of *lysE*, see 'subcloning and sequence analysis' in col. 1, page 818 and Fig. 2, page 817 (claims 7-9, 17, 46).

Conclusion

No claims are allowed.

Inquiries

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rita Mitra whose telephone number is (703) 605-1211. The Examiner can normally be reached from 9:30 a.m. to 6:30 p.m. on weekdays. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Dr. Christopher Low, can be reached at (703) 308-2923. Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Fax Center number is (703) 308-4242. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.



Rita Mitra, Ph.D.
October 19, 2001


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